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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WHISENANT, ETHAN C	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 12/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/086,941	PHAN ET AL.	
	Examiner	Art Unit	
	Ethan Whisenant, Ph.D.	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-115* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-115* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

ELECTION/RESTRICTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. **Claim(s) 1-28** drawn to a method of evaluating a solid phase for use in a dual bead assay, classified in Class 435, subclasses 6 and 7.1.

II. **Claim(s) 29-66 and 109-115** drawn to an optical bio-disc, classified in Class 435, subclasses 6 and 7.1.

III. **Claim(s) 67-92** drawn to a method of preparing a dual bead assay for use in an optical bio-disc which method comprises a step involving hybridization, classified in Class 435, subclass 6.

IV. **Claim(s) 93-95, 97 and 108** drawn to a method of testing for the presence of a target nucleic acid in a biological sample using a bio-disc and involving hybridization, classified in Class 435, subclass 6.

V. **Claim(s) 96-97, 104-106 and 108** drawn to a method of testing for the presence of a target antigen in a biological sample using a bio-disc and involving antigen-antibody binding, classified in Class 435, subclass 7.1.

VI. **Claim(s) 98-102, 107** drawn to a method of making an optical bio-disc comprising the use of nucleic acids and for use in a hybridization assay, classified in Class 435, subclasses 6.

VII. **Claim(s) 103-106, 107** drawn to a method of making an optical bio-disc, comprising the use of antigen(s) and antibodies (i.e. affinity binding partners) and for use in an assay comprising antigen-antibody binding (i.e. the binding of affinity binding partners), classified in Class 435, subclasses 6.classified in Class 435, subclass 7.1.

2. The inventions are distinct, each from the other for the following reasons.

Inventions I and II are related as a process of use and a product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used simply as a means to store and/or archive important nucleic acid sequences and/or proteins.

Inventions I and III are drawn to two patentably distinct processes, one i.e. Group I is drawn to a method of evaluating a solid phase for use in a dual bead assay and two i.e. Group III is drawn to a method of preparing a dual bead assay for use in an optical bio-disc which method comprises a step involving hybridization. These methods have different goals, different intermediate steps and different end results.

Inventions I and IV are drawn to two patentably distinct processes, one i.e. Group I is drawn to a method of evaluating a solid phase for use in a dual bead assay and two i.e. Group IV is drawn to a method of testing for the presence of a target nucleic acid in a biological sample using a bio-disc and involving hybridization. These methods have different goals, different intermediate steps and different end results.

Inventions I and V are drawn to two patentably distinct processes, one i.e. Group I is drawn to a method of evaluating a solid phase for use in a dual bead assay and two i.e. Group V is drawn to a method of testing for the presence of a target antigen in a biological sample using a bio-disc and involving antigen-antibody binding. These methods have different goals, different intermediate steps and different end results.

Inventions I and VI are drawn to two patentably distinct processes, one i.e. Group I is drawn to a method of evaluating a solid phase for use in a dual bead assay and two i.e. Group VI is drawn to a method of making an optical bio-disc comprising the use of nucleic acids and for use in a hybridization assay. These methods have different goals, different intermediate steps and different end results.

Inventions I and VII are drawn to two patentably distinct processes, one i.e. Group I is drawn to a method of evaluating a solid phase for use in a dual bead assay and two i.e. Group VII is

drawn to a method of making an optical bio-disc, comprising the use of antigen(s) and antibodies (i.e. affinity binding partners) and for use in an assay comprising antigen-antibody binding (i.e. the binding of affinity binding partners). These methods have different goals, different intermediate steps and different end results.

Inventions II and III are related as a product and a process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used simply as a means to store and/or archive important nucleic acid sequences and/or proteins.

Inventions II and IV are related as a product and a process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used simply as a means to store and/or archive important nucleic acid sequences and/or proteins.

Inventions II and V are related as a product and a process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used simply as a means to store and/or archive important nucleic acid sequences and/or proteins.

Inventions II and VI are related as a process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process.

Inventions II and VII are related as a process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by

another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process.

Inventions III and IV are drawn to two patentably distinct processes, one i.e. Group III is drawn to a method of preparing a dual bead assay for use in an optical bio-disc which method comprises a step involving hybridization and two i.e. Group IV is drawn to a method of testing for the presence of a target nucleic acid in a biological sample using a bio-disc and involving hybridization. These methods have different goals, different intermediate steps and different end results.

Inventions III and V are drawn to two patentably distinct processes, one i.e. Group III is drawn to a method of preparing a dual bead assay for use in an optical bio-disc which method comprises a step involving hybridization and two i.e. Group V is drawn to a method of testing for the presence of a target antigen in a biological sample using a bio-disc and involving antigen-antibody binding. These methods have different goals, different intermediate steps and different end results.

Inventions III and VI are drawn to two patentably distinct processes, one i.e. Group III is drawn to a method of preparing a dual bead assay for use in an optical bio-disc which method comprises a step involving hybridization and two i.e. Group VI is drawn to a method of making an optical bio-disc comprising the use of nucleic acids and for use in a hybridization assay. These methods have different goals, different intermediate steps and different end results.

Inventions III and VII are drawn to two patentably distinct processes, one i.e. Group III is drawn to a method of preparing a dual bead assay for use in an optical bio-disc which method comprises a step involving hybridization and two i.e. Group VII is drawn to a method of making an optical bio-disc, comprising the use of antigen(s) and antibodies (i.e. affinity binding partners) and for use in an assay comprising antigen-antibody binding (i.e. the binding of affinity binding partners). These methods have different goals, different intermediate steps and different end results.

Inventions IV and V are drawn to two patentably distinct processes, one i.e. Group IV is drawn to a method of testing for the presence of a target nucleic acid in a biological sample using a bio-disc and involving hybridization and two i.e. Group V is drawn to a method of testing for the presence of a target antigen in a biological sample using a bio-disc and involving antigen-antibody binding. These methods have different goals, different intermediate steps and different end results.

Inventions IV and VI are drawn to two patentably distinct processes, one i.e. Group IV is drawn to a method of testing for the presence of a target nucleic acid in a biological sample using a bio-disc and involving hybridization and two i.e. Group VI is drawn to a method of making an optical bio-disc comprising the use of nucleic acids and for use in a hybridization assay. These methods have different goals, different intermediate steps and different end results.

Inventions IV and VII are drawn to two patentably distinct processes, one i.e. Group IV is drawn to a method of testing for the presence of a target nucleic acid in a biological sample using a bio-disc and involving hybridization and two i.e. Group VII is drawn to a method of making an optical bio-disc, comprising the use of antigen(s) and antibodies (i.e. affinity binding partners) and for use in an assay comprising antigen-antibody binding (i.e. the binding of affinity binding partners). These methods have different goals, different intermediate steps and different end results.

Inventions V and VI are drawn to two patentably distinct processes, one i.e. Group V is drawn to a method of testing for the presence of a target antigen in a biological sample using a bio-disc and involving antigen-antibody binding and two i.e. Group VI is drawn to a method of making an optical bio-disc comprising the use of nucleic acids and for use in a hybridization assay. These methods have different goals, different intermediate steps and different end results.

Inventions V and VII are drawn to two patentably distinct processes, one i.e. Group V is drawn to a method of testing for the presence of a target antigen in a biological sample using a bio-disc and involving antigen-antibody binding and two i.e. Group VII is drawn to a method of making an optical bio-disc, comprising the use of antigen(s) and antibodies (i.e. affinity binding partners) and for use in an assay comprising antigen-antibody binding (i.e. the binding of affinity binding partners). These methods have different goals, different intermediate steps and different end results.

Inventions VI and VII are drawn to two patentably distinct processes, one i.e. Group VI is drawn to a method of making an optical bio-disc comprising the use of nucleic acids and for use in a hybridization assay and two i.e. Group VII is drawn to a method of making an optical bio-disc, comprising the use of antigen(s) and antibodies (i.e. affinity binding partners) and for use in an assay comprising antigen-antibody binding (i.e. the binding of affinity binding partners). These methods have different goals, different intermediate steps and different end results.

It is noted that Claim 107 has been placed into both of these groups. The other claims in each group is more narrow and limited to either a method utilizing nucleic acids or antigen-antibodies (i.e. the binding of affinity binding partners). This is because Claim 107 is a broad generic claim encompassing both species.

Upon election of one of these groups (Groups VI or VII) the applicant will be required to limit Claim 107 to either a method of making an optical bio-disc, comprising the use of nucleic acids or to a method of making an optical bio-disc, comprising the use of antigen/antibodies.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or the the necessity for non-coextensive literature searches, restriction for examination purposes as indicated is proper.

4. A telephone call was made to the applicant's representative to request an oral election to the above restriction requirement, but did not result in an election being made.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments

submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

CONCLUSION

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (703) 308-6567. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

The fax number for this Examiner is (703) 746-8465. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196.

♦Please note that the USPTO is scheduled to relocate to its new home in Alexandria, VA very soon (JAN 04'). As a result, t he examiner's telephone and desktop FAX numbers will be changing. The new telephone and desktop FAX numbers for Ethan Whisenant, Ph.D. are/will be as shown below:
New Telephone number : (571) 272-0754
New FAX number : (571) 273-0754.

ETHAN WHISENANT
PRIMARY EXAMINER